K090991

510(k) Summary

OCT - 9 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: Mar. 25, 2009

1. Company and Correspondent making the submission:

Name – E-WOO Technology Co., Ltd.
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Contact – Mr. DongTaek, Oh
Internet – http://www.e-wootech.com

2. Device :

Trade/proprietary name	: Picasso-Duo
Common Name	: Computed tomography x-ray system
Classification Name	: Computed tomography x-ray system

3. Predicate Device

Predicate Device A:

Manufacturer	: VATECH Co., Ltd.
Device	: PaX-500
510(k) Number	: K082350 (Decision Date - Oct. 10. 2008)

Predicate Device B:

Manufacturer	: E-WOO Technology Co., Ltd.
Device	: EPX-Impla: Picasso-Trio
510(k) Number	: K070658 (Decision Date - Apr. 5. 2007)

4. Classifications Names & Citations :

21CFR 892.1750, OAS, Computed tomography x-ray system, Class2

5. Description :

5.1 General

E-WOO Dental Imaging system Picasso-Duo is a Computed Tomography X-ray System. Computed Tomography (CT) provides valuable 3-D imaging of the dental and maxillofacial structures for diagnosis and treatment planning. Uses of CT imaging include for assessment of impacted teeth, root configurations and mandibular condyle evaluation. This technology allow for 3-D imaging but at lower equipment cost, simpler image acquisition and lower patient radiation dose.

Model Picasso-Duo is diagnostic equipment which consists of panoramic dental x-ray system and computed tomography x-ray system. The panoramic dental x-ray is a system based on digital and computed tomography (CMOS CT Sensor to Capture 3D x-ray Computerized tomogram scanned image)

5.2 Product features

- Picasso-Duo, the dental CT system with digital panoramic unit, provides the high quality digital image.
- It is not necessary to attach / detach the panoramic sensor when you capture CT images by Auto-Switching system.
- It is possible to capture Maxillary, mandible and whole arch by wider FOV (15 * 15).
- With Picasso-Trio it is not required to purchase a CT and a panoramic system each separately.
- It is helpful for treatments by viewing the invisible part with a 3-D CT images.
- The disk space for installation is no bigger than that of a general panoramic system.
- A clear Tomography image upto minimum 0.1mm at any directions
- You can set and control the Examination Program Mode with a console PC
- Support more accurate diagnosis imaging than LCD as well as voice announcement function for patients and staffs
- Picasso-Duo supports the DICOM Format

5 Indication for use :

The Picasso-Duo is a computed tomography x-ray system which is a diagnostic x-ray system intended to produce cross-sectional images(optionally with panoramic) for dental examination and diagnosis of diseases of the teeth, jaw and oral structure by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles.

6 Comparison with predicate device :

E-WOO Technology Co., Ltd., believes that the Picasso-Duo is substantially equivalent to the EPX-Impla of E-WOO Technology Co., Ltd. and PaX-500 of VATECH Co., Ltd.

7 Safety, EMC and Performance Data :

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1, IEC 60601-1-1, IEC 60601-1-3, IEC 60601-2-7, IEC 60601-2-28, IEC 60601-2-32 and IEC 60601-2-44 was performed, and EMC testing was conducted in accordance with standard IEC 60601-1-2. All test results were satisfactory.

9. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification E-WOO Technology Co., Ltd. concludes that The Picasso-Duo is safe and effective and substantially equivalent to predicate devices as described herein.

10. E-WOO Technology Co., Ltd. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

OCT - 9 2009

E-Woo Technology
c/o Mr. Vincent Lee
E-Woo Technology USA, Inc.
256 North Sam Houston Pkwy. E, Suite 115
HOUSTON TX 77060

Re: K090991
Trade/Device Name: Computed tomography x-ray system /Picasso-Duo
Regulation Number: 21 CFR §892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: September 22, 2009
Received: September 24, 2009

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number(if known): K090991

Device Name: Computed tomography x-ray system /Picasso-Duo

Indications for Use:

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Prescription Use ✓ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K090991